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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,188	10/15/2003	Edward T. Wei		7569

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Edward T. Wei  
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EXAMINER

JONES, DAMERON LEVEST

ART UNIT PAPER NUMBER

1618

DATE MAILED: 12/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/687,188

Applicant(s)

WEI, EDWARD T.

Examiner

D. L. Jones

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 6,9,10 and 17-25 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 11-16 is/are allowed.
- 6) ☒ Claim(s) 1-5,7,8 and 26-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 9/15/05.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 9/15/05 wherein claims 26-35 were added.

**Note:** Claims 1-35 are pending.

## APPLICANT'S INVENTION

2. Applicant's invention is directed to N-radiohaloaryl alkylcarboxamide radioligands.

## APPLICANT'S ELECTION

3. Applicant's election with traverse of Group II directed to radioligands wherein the alkyl moiety is a cyclohexane or a composition thereof having the formula as set forth in independent claim 11 filed 9/15/05. In addition, the Examiner acknowledges receipt of Applicant's election of the species wherein the alkyl moiety of the radioligand is ((1R,2S,5R)-2-isopropyl-5-methyl-cyclohexyl. The traversal is on the ground that Applicant believes that 35 USC 121 requires a showing of both independence and distinctness before requiring a restriction. This is found non-persuasive because there are two criteria for restriction between patentably distinct inventions is as follows: (1) the invention must be independent or distinct; and (2) searching of the full scope of the invention would be a serious burden on the Examiner. Thus, a showing of both independence and distinctness is not necessary. Also, it is noted that searching the full

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scope of the instant invention is a serious burden on the Examiner because, for example, Formula 1 is very different from Formula 2 since in Formula 1 R is a saturated or monoethylenically unsaturated alkyl substituted cyclic or bicyclic alkyl radical having 7-14 carbon atoms selected from cyclopentanes, cyclohexanes, cycloheptanes, cyclooctanes, cyclononanes, bicycloheptanes, bicyclohept-5-enes, bicyclooctanes and bicyclooct-5-enes whereas Formula 2 lacks the cyclic or bicyclic alkyl radical attachment and contains a spacer between CONHY and R'R''R'''. As a result, a separate search of the art is necessary for each invention. Also, prior art, which anticipates or renders obvious one invention would neither anticipate nor render obvious the other groups. Hence, the restriction requirement is still deemed proper and is therefore made FINAL.

**Note:** In regards to Applicant's assertions that the instant invention does not disclose any process claims, but product claims only, Applicant is respectfully requested to review claims 9 and 10 which disclose the use of the radioligand. It should be noted that 'use of' claims are generally intended to be method of use claims and are usually amended as such.

#### **WITHDRAWN CLAIMS**

4. Claims 6, 9, 10, and 17-25 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention/species.

#### **112 FIRST PARAGRAPH REJECTIONS (New Matter)**

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 34 and 35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims contain new matter for the following reasons. (1) Throughout the specification, the formula is RCONHY, not R'CONHY. One cannot arbitrarily make up a formula that is directed to the elected species without having support for that formula in the specification. (2) In addition, the definition of the phrase 'Y is a substituted phenylethyl-' is not consistent with the disclosure of the specification. In particular, the specification discloses that the variable Y is substituted aromatic radical containing substituents R1, R2, and X. The variable Y is attached directly to the NH group. However, when the phrase 'Y is a substituted phenylethyl-' is used, it indicates that the variable Y is attached to the NH group through the 'ethyl' group which may be called a spacer group. Review of the specification discloses direct linkage to the NH, not the use of a spacer group. Applicant is reminded that the interpretation of the phrase '-phenylethyl' is different from 'phenylethyl-' because '-phenylethyl' indicates that attachment is through the phenyl group (the phenyl group is substituted with an ethyl group).

## 112 SECOND PARAGRAPH REJECTIONS

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-5, 7, 8, and 26-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-5, 7, and 8: Independent claim 1 is ambiguous because it is unclear what is intended by the phrase 'the alkyl moiety thereof is provided by a branched hydrophobic carbon unit'. Is Applicant saying that the alkyl moiety contains a branched hydrophobic carbon unit? Thus, since the independent claim is ambiguous, those claims depending thereof are also ambiguous.

Claim 5: Did Applicant intend to write 'R' instead of 'R-'?

Claims 8 and 26-33: The claim as written is ambiguous because claims 8, 26, 30, and 31 contain improper Markush terminology. The term 'includes' is open and Markush claims require closed terminology (Applicant is respectfully requested to review MPEP 803.02) for acceptable Markush terminology). Thus, since claims 27-33 depend on claim 26 which is ambiguous, those claims are ambiguous as well.

Claim 30: The claim as written is ambiguous because of 'R-'. Did Applicant intend to write 'R'?

Claims 34 and 35: In claim 34, line 2, did Applicant intend to write 'R'? Since claim 35 depends upon claim 34 which is indefinite, then claim 35 is indefinite as well.

### **ALLOWABLE CLAIMS**

9. Claims 11-16 are free of the prior art of record for the reasons set forth below.

### **COMMENTS/NOTES**

10. It should be noted that no prior art has been cited against the instant invention. However, Applicant **MUST** address and overcome the 112 rejections above. The claims are distinguished over the prior art of record because the prior art neither anticipates nor renders obvious radioligands as set forth in Applicant's elected invention.

11. It should be noted that the search has not been extended beyond elected Group 1 which is directed to a N-radiohaloaryl alkylcarboxamide radioligand of Formula 1 wherein R is cyclohexane. Applicant is respectfully requested to cancel the non-elected subject matter.

12. The lined through documents on the information disclosure statement were not present in the application during examination. If Applicant would like those documents considered, it is respectfully requested that those documents be submitted with the next correspondence to the Examiner.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to be 'D. L. Jones', with a stylized, cursive script.

D. L. Jones  
Primary Examiner  
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December 19, 2005